UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN

WYETH,

Plaintiff,

v.

SUN PHARMACEUTICAL INDUSTRIES LTD. and CARACO PHARMACEUTICAL LABORATORIES LTD.,

JURY TRIAL DEMANDED

Defendants.

COMPLAINT

This is a complaint for, among other things, false advertising under the Lanham Act, 15 U.S.C. § 1125, and deceptive trade practices under the Michigan Consumer Protection Act, Mich. Comp. Laws §445.901, relating to the advertising and sale by defendants of what purports to be a generic form of Protonix®, a prescription drug manufactured and sold by Wyeth and indicated for the treatment of certain gastrointestinal disorders.

PARTIES

1. The plaintiff Wyeth is a Delaware corporation with a place of business at Five Giralda Farms, Madison, New Jersey 07940.

2. Upon information and belief, defendant Sun Pharmaceutical Industries, Ltd. ("Sun") is a public limited liability company incorporated and existing under the laws of India, and having a principal place of business at Acme Plaza, Andheri Kurla Road, Andheri (East) Mumbai 400059, Maharashtra, India.

3. Upon information and belief, defendant Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") is a Michigan corporation having a principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202. Upon information and belief, Caraco is a subsidiary of Sun.

JURISDICTION AND VENUE

4. This court has subject matter jurisdiction over Wyeth's claims because they arise under the Lanham Act, 15 U.S.C. §1051 *et seq.*, and because the parties are completely diverse and the amount in controversy exceeds $75,000. Federal subject matter jurisdiction is therefore conferred by 29 U.S.C. §§1331, 1332 (federal question and diversity), 28 U.S.C. §1338(b) (unfair competition), and 15 U.S.C. §1121 (Lanham Act). This court has supplemental jurisdiction over Wyeth's state law claims pursuant to 28 U.S.C. §1367.

5. Sun is subject to personal jurisdiction in this judicial district because, on information and belief, Sun does and/or transacts business within this State and District, and has made and established contacts sufficient to permit the exercise of personal jurisdiction under Mich. Comp. Laws §605.705.

6. Caraco is subject to personal jurisdiction in this judicial district because, upon information and belief, Caraco is a Michigan corporation having its principal place of business within this District.

7. Venue for this action is proper in this District pursuant to 29 U.S.C. §1391(b) & (c).

FACTUAL BACKGROUND

8. Wyeth manufactures and sells Protonix® tablets, a prescription pharmaceutical containing pantoprazole sodium sesquihydrate as the active ingredient. Wyeth also manufactures and sells its own generic form of Protonix® tablets which also contain pantoprazole sodium sesquihydrate as the active ingredient. Wyeth's Protonix® and generic pantoprazole sodium sesquihydrate tablets are sold throughout the United States, including in this District.

9. Protonix® belongs to a class of drugs known as proton pump inhibitors that inhibit gastric acid secretion. Protonix® is approved by the FDA for the treatment of various gastrointestinal disorders, including erosive esophagitis associated with gastroesophageal reflux disease (GERD) and pathological hypersecretory conditions.

10. Protonix® is one of Wyeth's most successful products. Before Sun and Caraco, and others, began selling their generic versions of Protonix® tablets, annual sales of Protonix® in the United States were nearly $2 billion.

11. To obtain approval to market Protonix® in the United States, Wyeth was required to submit a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA"). This NDA included the results of extensive clinical trials with pantoprazole sodium sesquihydrate, conducted over the course of many years, at a cost of hundreds of millions of dollars. The clinical trials conducted by Wyeth were designed to establish the safety and efficacy of pantoprazole sodium sesquihydrate. Wyeth received FDA approval to sell Protonix® tablets on February 2, 2000.

12. Sun, a generic drug manufacturer based in India, filed an abbreviated application with the FDA in 2004 seeking approval to market and sell a generic version of Protonix® tablets.

In doing so, it relied on the clinical studies and data Wyeth submitted for Protonix®. In a letter to Wyeth dated May 5, 2004, Sun stated that the active ingredient in its proposed generic version of Protonix® tablets would be pantoprazole sodium sesquihydrate.

13. The FDA approved Sun's application to market generic Protonix® tablets in September 2007. Upon information and belief, the FDA approved Sun's application for generic Protonix® tablets based, in part, on Sun's representation that it intended to sell a tablet containing pantoprazole sodium sesquihydrate as the active ingredient. Upon information and belief, the FDA granted Sun approval to sell a tablet containing pantoprazole sodium sesquihydrate as the active ingredient.

14. Sun, and its subsidiary Caraco, began selling pantoprazole tablets with a product package insert representing that those tablets contained pantoprazole sodium sesquihydrate as the active ingredient throughout the United States, including, upon information and belief, in this District, in January 2008. Upon information and belief, Sun and Caraco continue to sell these tablets. Sun and Caraco's tablets directly compete with Wyeth's Protonix® tablets, as well as Wyeth's own generic form of Protonix® tablets.

15. The package insert for Sun and Caraco's tablets states that the tablets contain pantoprazole sodium ***sesquihydrate*** as the active ingredient. The package insert describes the clinical trials conducted by Wyeth using pantoprazole sodium ***sesquihydrate*** and provides information regarding pharmacology, side effects, indications and usage, contraindications, and dosage forms for pantoprazole sodium ***sesquihydrate***. This information is the same as that for Wyeth's Protonix® and Wyeth's own generic tablets. Sun's and Caraco's websites state that they are selling a generic form of Protonix®:

http://www.sunpharma.com/admin/news/upload/353.pdf;

http://www.caraco.com/ProductList.htm.

16. Despite expressly representing to the public that they are selling pantoprazole sodium ***sesquihydrate*** tablets, Sun and Caraco are actually selling tablets containing a different polymorphic form of pantoprazole sodium, pantoprazole sodium ***monohydrate***.

17. Polymorphs are different crystal forms of the same chemical compound. Polymorphs of a compound share the same chemical formula and molecular structure, but have different crystal forms, and therefore can have different properties, including melting point, stability, dissolution, and bioavailability. The FDA has stated that different polymorphic forms of a drug substance (including different hydrate forms) can have different chemical and physical properties that can have a direct effect on drug product stability, dissolution, and bioavailability, which ultimately can affect the quality, safety, and efficacy of the drug product. *See* FDA Guidance for Industry, ANDAs: Pharmaceutical Solid Polymorphism (July 2007). Pantoprazole sodium can exist in different polymorphic forms.

18. As part of the FDA approval process for Protonix® tablets, the FDA required Wyeth to add tests to the pantoprazole sodium sesquihydrate drug specification to differentiate the sesquihydrate form from other polymorphic forms, including pantoprazole sodium monohydrate, and to provide evidence that the sesquihydrate form (and not any other hydrate form) was used in all clinical batches.

19. Upon information and belief, neither Sun nor Caraco sought or obtained approval to sell tablets containing pantoprazole sodium monohydrate as the active ingredient.

20. By selling pantoprazole sodium ***monohydrate*** tablets labeled as containing pantoprazole sodium ***sesquihydrate*** as the active ingredient, Sun is making a literally false statement regarding the active ingredient of its pharmaceutical product, in violation of the Lanham Act.

21. Sun and Caraco's product package insert misleads consumers by falsely representing that their product contains pantoprazole sodium sesquihydrate and by including safety and efficacy data for pantoprazole sodium sesquihydrate, thereby suggesting to the public that their tablets have undergone a rigorous testing process and that FDA has approved Sun and Caraco to sell their product. However, upon information and belief, FDA has not approved the sale of pantoprazole sodium monohydrate. This false advertising has enabled Sun and Caraco to garner a portion of the sales to consumers seeking pantoprazole sodium sesquihydrate tablets, the very same consumers for which Protonix® and Wyeth's own generic tablets compete.

22. Upon information and belief, neither Sun nor Caraco has shown that pantoprazole sodium monohydrate has the same stability, dissolution, bioavailability, quality, safety or efficacy as pantoprazole sodium sesquihydrate.

23. Sun and Caraco's mislabeled tablets directly compete with Wyeth's Protonix® tablets and Wyeth's generic version of Protonix® tablets.

24. Upon information and belief, Sun and Caraco's deceptive advertising and labeling has influenced consumers' decisions to purchase their pantoprazole tablets instead of one of Wyeth's pantoprazole tablets.

COUNT ONE

(False Advertising, Lanham Act §1125)

25. Wyeth incorporates the allegations contained in the preceding paragraphs as if fully set forth herein.

26. The defendants' product package insert, including as described above, contains false and misleading statements.

27. The defendants' false and misleading statements go to an inherent quality or characteristic of the defendants' product.

28. Upon information and belief, the defendants' false and misleading statements have influenced consumers' purchasing decisions in this District and elsewhere and will continue to do so unless enjoined.

29. Wyeth has suffered and will continue to suffer actual damages unless the defendants' conduct is enjoined.

COUNT TWO

(Unfair Competition)

30. Wyeth incorporates the allegations contained in the preceding paragraphs as if fully set forth herein.

31. The defendants' product package insert, including as described above, contains false and misleading statements.

32. The defendants' false and misleading statements go to an inherent quality or characteristic of the defendants' product.

33. Upon information and belief, the defendants' false and misleading statements have influenced consumers' purchasing decisions in this District and elsewhere and will continue to do so unless enjoined.

34. Wyeth has suffered and will continue to suffer actual damages unless the defendants' conduct is enjoined.

COUNT THREE

(Tortious Interference with Business Expectancy)

35. Wyeth incorporates the allegations contained in the preceding paragraphs as if fully set forth herein.

36. The defendants know that Wyeth sells and has sold Protonix® tablets and its own generic version of Protonix® tablets to customers in this state and throughout the United States.

37. Wyeth had a reasonable likelihood of future economic benefit from the continued sales of Protonix® tablets and its own generic version of Protonix® tablets to customers in this state and throughout the United States.

38. Upon information and belief, the defendants intentionally and improperly interfered with Wyeth's customers by offering and selling a product that the defendants misrepresented to consumers as containing an active ingredient that is identical to Wyeth's products.

39. The defendants' product package insert, including as described above, contains false and misleading statements.

40. Upon information and belief, the defendants' false and misleading statements have influenced consumers' purchasing decisions in this District and elsewhere and has disrupted Wyeth's sales to consumers, and will continue to do so unless enjoined.

41. Wyeth has suffered and will continue to suffer actual damages unless the defendants' conduct is enjoined.

COUNT FOUR

(Deceptive Trade Practices – Michigan Consumer Protection Act)

42. Wyeth incorporates the allegations contained in the preceding paragraphs as if fully set forth herein.

43. The defendants' product package insert, including as described above, contains false and misleading statements, in violation of the Michigan Consumer Protection Act, Mich. Comp. Laws §445.903.

44. The defendants' false and misleading statements go to an inherent quality or characteristic of the defendants' product, in violation of the Michigan Consumer Protection Act, Mich. Comp. Laws §445.903.

45. Upon information and belief, the defendants' false and misleading statements have influenced consumers' purchasing decisions in this District and elsewhere and will continue to do so unless enjoined.

46. Wyeth has suffered and will continue to suffer actual damages unless the defendants' conduct is enjoined.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff Wyeth respectfully requests that this Court:

1. Enter judgment in favor of Wyeth on each of its claims;

2. Preliminarily and permanently enjoin the defendants and their predecessors, successors, divisions, subsidiaries, or joint ventures thereof, together with any and all parent or affiliated companies or corporations, and all officers, directors, employees, agents, attorneys, representatives, those acting in privity or concert with them, or on their behalf, from further sale of pantoprazole sodium monohydrate under a label and product insert for pantoprazole sodium sesquihydrate.

3. Award Wyeth its actual damages in an amount to be determined at trial;

4. Award Wyeth all of its actual costs and reasonable attorneys' fees in this action, as authorized by 15 U.S.C. §1117 and Mich. Comp. Laws §445.911;

5. Award Wyeth an accounting of defendants' profits as authorized by 15 U.S.C. §1117; and

6. Grant to Wyeth such other relief as may be just and warranted under the circumstances.

JURY DEMAND

Plaintiff Wyeth demands a trial by jury on all issues so triable.

Respectfully submitted,

Dated: May 5, 2009

KERR, RUSSELL AND WEBER, PLC

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